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REGULATORY GUIDE
NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE DEPARTMENT

REGULATORY GUIDE 7.0
GUIDE FOR APPLICATION PREPARATION FOR MEDICAL USE PROGRAMS

1. INTRODUCTION

1.1 GENERAL

The Nebraska Health and Human Services Regulation and Licensure Department regulates the intentional internal or external administration of radioactive material, or the radiation therefrom, to humans for medical use. A specific license of either limited or broad scope is issued to authorize possession and use of licensed material. These licenses are issued pursuant to 180 NAC 1 Section 003 and Section 007.

The Agency usually issues a single radioactive material license to cover an entire radioisotope program except for teletherapy, nuclear-powered pacemakers and irradiators. The teletherapy license will include the authorization for source material (i.e., depleted uranium) contained as shielding in many teletherapy units. Separate licenses are not usually issued to different departments within a medical facility or to individuals employed by or contracted to the medical facility. If the application is for medical use sited in a medical institution (hospitals, university medical centers, some group physician practices), only the institution's management may apply for the license. If the application is for medical use not sited in a medical institution (private practice physician, some clinics), any person may apply. A licensee applicant should carefully study this guide, related guidance and all applicable regulations prior to completing the Agency application form, NRH-5A, "Application for Radioactive Material License - Medical or Teletherapy".

NEBRASKA HEALTH & HUMAN SERVICES REGULATION AND LICENSURE DEPARTMENT,
REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public acceptable methods of implementing specific parts of 180 NAC 1 (Nebraska Regulations for Control of Radiation-Ionizing), to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the Nebraska Health and Human Services Regulation and Licensure Department, Public Health Assurance Division, to make necessary determination to issue or continue a license or certificate of registration.

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the Nebraska Health and Human Services, Regulation and Licensure Department,Public Health Assurance Division, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509.

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In order to provide the Agency with information on specifics of the proposed radiation safety program as requested by Form NRH-5A, it is expected that licensees will submit attachments to Form NRH-5A to provide such information. When necessary, the Agency may request additional information to provide reasonable assurance that the applicant has established an adequate radiation protection program. After a license is issued, the licensee must conduct its program in accordance with: (1) the statements, representations, and procedures contained in the application and correspondence with the Agency, (2) the terms and conditions of the license, and (3) the Agency's regulations. NRH-5A "Application for Radioactive Material License – Medical or Teletherapy" requires that all information provided is "true and correct". Information is considered to be material if it is likely to change or affect an agency decision on issuing the license. The information collections discussed in this draft regulatory guide are covered by Agency Form NRH-5A, "Application for Radioactive Material License – Medical or Teletherapy".

1.1.1 PURPOSE OF THE GUIDE

The purpose of this regulatory guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments and license renewals that authorize possession of radioactive material for medical use, including teletherapy. This guide is intended to provide the applicant or licensee with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to medical licenses. Regulatory guides are also issued to describe and make available to the public methods acceptable to the Agency staff for implementing specific parts of the Agency's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated problems, or to provide guidance to applicants. The information provided in this guide does not constitute regulatory requirements; however, applicants should address all the items on Agency Form NRH-5A and should either follow the specific guidance in this guide or provide responses to the items adequately to assure safe operation and compliance with applicable regulations.

1.1.2 PURPOSE OF THE APPENDICES TO THE GUIDE

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through S to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and then decide if the model procedure appropriately addresses its specific radiation program needs. In the application, applicants may certify that they will follow a model procedure (appropriate certification language is given at the beginning of each appendix) or may say that they have developed a procedure that is analogous and is enclosed for Agency review (appropriate reference language is given at the beginning of each appendix).

1.2 APPLICABLE REGULATIONS

Agency regulations applicable to medical uses are described in 180 NAC Section 010, "Notices, Instructions, and Reports to Workers; Inspections"; 180 NAC Section 004, "Standards for Protection Against Radiation"; 180 NAC Section 003, " Licensing of Radioactive Material"; 180 NAC Section 7, "Medical Use of Radioactive Material"; 180 NAC Section 18, "Fees for Certificates of Registration, Radioactive Material(s) Licenses, Environmental Surveillance, Emergency Response and other Regulatory Services". It is your responsibility as an applicant and licensee to have copies of, to read and to abide by each regulation. As a licensee, you are subject to all applicable provisions of the regulations as they pertain to medical use.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraphs 004.05A and 004.05B of revised 180 NAC, Section 004, effective September 17, 1997, state that "each licensee must develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of section 4.... and "the licensee shall use, to the extent practicable, procedures and controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA)." Additionally, this section requires that licensees review the radiation protection program content and implementation at least annually. Draft NUREG-1516 (NUREGs are produced by the Nuclear Regulatory Commission (NRC)) provides guidance on the conduct of audits of radiation safety programs including the ALARA portion.

Nebraska Regulatory Guide 4.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures ALARA, and 4.11, Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions will be ALARA," provide the Agency staff position on this subject. Applicants should consider the ALARA philosophy as described in these guides in developing plans for work with licensed radioactive materials. Many NRC publications are available through the Internet site http://www.nrc.gov/NRC/RG/index.html.

1.3.1 GENERAL ALARA CONSIDERATIONS

Each individual who is authorized to use radioactive material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material and should ensure that the facility and equipment are adequate for safe use. NUREG-1134, "Radiation Protection Training for Personnel Employed in Medical Facilities," and Draft NUREG-1516, "Effective Management of Radioactive Material Safety Programs at Medical Facilities," provide information on training programs for use by medical use licensees. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or RSO. This issue is also discussed in Draft NUREG-1516. The NRC issued Draft NUREG-1516, "Effective Management of Radioactive Materials Safety Programs at Medical Facilities," in January 1995, to provide guidance on effectively managing radiation safety programs by emphasizing a team approach to program management. Team members include executive management of the licensed facility, the Radiation Safety Committee (RSC) and Radiation Safety Officer (RSO). The NUREG also discusses the duties and responsibilities of the RSO and supervised individuals; conduct of required audits; pros and cons of the use of consultants or service companies to augment the radiation safety program; resources that may be needed to support the program; and Agency notification and reporting requirements. Several appendices are included to provide specific tools for day-to-day operation of a radiation safety program. Additionally, an extensive annotated bibliography identifies publications on radiation safety program management at medical facilities. It is expected that this NUREG may provide licensees with effective tools in managing their licensed programs.

1.3.2 ALARA IN MEDICAL INSTITUTIONS

Each medical licensee must have a formal ALARA program (see 180 NAC 1-004.05 and 007.09). The success of the ALARA program depends on the cooperation of each person who works at the licensed facility. Management should make a commitment to the ALARA philosophy and implement that commitment with adequate resources. A Radiation Safety Committee composed of individuals who have special expertise in the safe use of radioactive material is required by 180 NAC 1-007.11 to review uses for safety and ALARA considerations. The RSC, Radiation Safety Officer, and management should audit the radioactive material program to ensure the continued safe use of radioactive material. In addition to being a member of the Committee, the RSO serves as a technical consultant to the Committee and is also responsible for the day-to-day operation of the radiation safety program.

A model ALARA management program is contained in Appendix B3 to this guide. Several other Nebraska HHS R+L publications contain background information on the ALARA philosophy and its application in the medical environment. For example, Nebraska Regulatory Guide 4.10 and NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions ALARA", contain information, methods, and references useful in establishing radiation safety programs to maintain exposures ALARA in medical institutions. Applicants should consider the ALARA philosophy in the development of plans for work with radioactive materials.

1.4 TYPES OF LICENSES

The Agency issues three types of licenses for the medical use of radioactive material. They are described below. This guide is only for persons who want to apply for a specific medical use license. However, persons who are to applying for other types of licenses may find the information in this guide useful in designing their radiation safety program.

1.4.1 GENERAL LICENSE

180 NAC 1 Section 003, "Licensing of Radioactive Material," establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use certain small quantities of radioactive material for in-vitro clinical or laboratory tests not involving medical use (that is, not involving administration to humans). 180 NAC 1 Section 003.07I explains the requirements for using materials listed in that section. If the general license alone meets the applicant's needs, only NRH Form 17, "Certificate - In Vitro Testing with Radioactive Material Under General License", needs to be filed. Medical use licensees authorized pursuant to 180 NAC 1-007 do not need to file the form. The use of materials listed in 003.07I within the inventory limits of that section will only be subject to the requirements of that section and not subject to the requirements of 180 NAC Sections 4 and 10, except as provided in 003.07I6.

1.4.2 SPECIFIC LICENSE

Specific licenses for physicians in private practice are generally limited to a physician who is located in a private office, that practices a limited number of medical disciplines, and whose practice is not sited within a licensed medical institution. For this group of licensees, a RSC is not required and procedures requiring hospitalization of the patient are not authorized to be performed.

Specific licenses are also issued to medical institutions. A medical institution is an organization in which several medical disciplines are practiced. These licenses authorize radioactive material for medical uses by physicians named on the institution's license or authorized by the licensee in accordance with 180 NAC 1-007. A medical institution must have a RSC to oversee the safe use of licensed material throughout the institution and to review the institution's radiation safety program.

A specific license may also be issued for a mobile nuclear medicine service (180 NAC 1-007.15). Both private practice physicians and medical institutions may apply for authorization to use radioactive material in a mobile service.

1.4.3 SPECIFIC LICENSE OF BROAD SCOPE

Some medical institutions provide patient care and conduct research programs that use radioisotopes for in vitro, animal, and medical procedures. In these cases, the Agency may issue a specific license of broad scope as discussed in 180 NAC Section 003, "Licensing of Radioactive Material." Specific licenses of broad scope for medical use, i.e., license authorizing multiple quantities and types of radioactive material for unspecified uses, are issued to institutions that: 1) have had previous experience successfully operating under a specific institutional license of limited scope; and 2) are engaged in

medical research as well as routine diagnostic and therapy using radioactive material. Refer to NUREG-1556, Vol 11, "Consolidated Guidance About Materials Licenses, Program Specific Guidance About Broad Scope Licenses", for guidance on applying for a medical use license of broad scope.

2. FILING AN APPLICATION

2.1 WHERE TO FILE

To file an application with the State of Nebraska, the application package should be forwarded to HHS Regulation and Licensure, 301 Centennial Mall South P.O. Box 95007, Lincoln, NE, 68509-5007. The Nuclear Regulatory Commission has jurisdiction for the possession or use of radioactive material in 20 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands and U.S. Territories. These states are referred to as non-Agreement states. The other 30 states have entered into an agreement with the NRC that gives them the authority to license radioactive materials used or possessed within their borders. These States are referred to as Agreement States. However, there is an exception. If licensed activities are to be conducted by a Federal facility, the license would be issued by NRC regardless of where the Federal facility is geographically located. If you are a non-Federal organization that wishes to possess or use licensed material in one of these Agreement States, the application should be filed with the State's radiation control program and not with the NRC.

2.2 HOW TO FILE

To apply for a medical use license, complete Agency Form NRH-5A - Medical and Teletherapy (See Exhibit 1 of this guide). Complete items 1 through 6, 24, 25 and 26 on the form itself. For items 7 through 23, submit information on supplementary pages and refer to them as attachments. Identify the attachment and number it to correspond to the form item to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8.5 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8.5 x 11 inches. It is not necessary to submit original or copies of facility blueprints. Complete all items on the application in sufficient detail for the Agency to determine that equipment, facilities, training and experience, and the radiation safety program are adequate to protect health and safety and minimize danger to life and property.

All license applications will be made available for review by the general public. Do not submit proprietary information unless it is absolutely necessary.

Personal information about employees should not be submitted unless it is absolutely necessary. For example, training and experience of employees should be substituted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses, home telephone numbers, dates of birth, social security numbers, and radiation dose information should not be submitted unless specifically requested by the Agency. An additional copy should be retained for future reference.

3. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on Agency Form NRH-5A (Medical). Form items 6 through 24 request specific information on the proposed radiation safety program. To assist the applicant in submitting complete information on these items, the applicable regulations are referenced in the discussion of each item, and an acceptable response is provided for your consideration and use.

As mentioned previously, this guide contains several appendices that present sample procedures and sample programs. You may wish to adopt one or more of these samples as part of your program. If so, you may adapt the following paragraph as a response to the appropriate item in your application:

> Item ___: We, (name of applicant), have established and agree to follow the procedures for ____ as described in Appendix____ in Regulatory Guide ____, dated_____.

In your application, if you refer to a section of this guide or of any regulatory guide, that section or appendix will be incorporated as a part of the terms and conditions of your license. You will be inspected against the commitments contained in the referenced section, appendix or document, just as you will be inspected against your more detailed responses. Therefore, you must keep a copy of the referenced guide on hand at all times so that you can review your commitments as necessary.

The exhibits following the appendices include copies of the application form (Agency Form NRH5-A, Exhibit 1); Form Supplements A, B, and C (Exhibits 2, 3, and 4) that may be used to document training and experience, the Resident's Support Technology TrainingTask Log (Exhibit 5) and Resident's Clinical Procedures Training Log (Exhibit 6).
If you have questions after careful review of this guide, contact HHS Regulation and Licensure, Radioactive Materials Program, 301 Centennial Mall South P.O. Box 95007, Lincoln, NE, 68509-5007 (Phone 402-471-2168).

The following discussion applies to the indicated items of Form NRH-5A (Medical)

ITEM 1 - LICENSE INFORMATION

1.a - APPLICANT'S NAME AND MAILING ADDRESS

If you are an individual, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive materials is not connected with your employment with a corporation or other legal entity. Otherwise, you the applicant, should be the corporation or other legal entity applying for the license. The legal name of the corporation or other legal entity applying for the license should be provided. The address specified here should be the complete mailing address for correspondence and may contain a Post Office box number, a department name, a mailing code or other information that will assist in getting mail to the applicant. This may or may not be the same as the address at which licensed material will be used, as specified in Item 1b. In general, an "attention" line should be included in the address, but that line should specify a title rather than a particular person's name.

Note that, in the case of teletherapy, paragraph 007.06A of 180 NAC 1 Section 007 provides that a license may be issued in the name of any person if the unit and source are not to be sited in a medical institution. Otherwise, the applicant should be the medical institution's management in which the unit and source is to be sited.

1.b - ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Specify each proposed location of use by the street address (including building name and other locating information, if appropriate), city, and state or other descriptive address (e.g., 5 miles east on Highway 10, Anytown, Nebraska) to allow the

Agency to facilitate locating the facility. A Post Office box address is not acceptable. If radioactive material is to be used at more than one location under the license, each specific address (e.g., street, building) must be provided. In addition, identify facilities designed or established for special uses associated with licensed activities, e.g., incinerators, waste compactors; waste storage facilities. In Items 7 through 24 of the application, describe the intended use and the facilities and equipment at each location.

ITEM 2 - NAME OF PERSON TO BE CONTACTED ABOUT APPLICATION

Provide the name of the individual who is cognizant of the proposed radiation safety program and can answer questions about the application. Provide the individual's work phone number in the event that Agency needs to contact the individual with questions about the application. If the contact person changes, notify the Agency.

The individual named in item 5 may or may not be the same individual who signs the application as the "certifying official" on behalf of the licensee and has the authority to make commitments to the Agency (see form item 26). Any commitments made by the applicant should be signed by the individual named in item 26 since only that individual is considered by the Agency to have the authority to make commitments on behalf of the applicant. Therefore, license amendments or renewals signed by the individual identified in item 5, if this is a different individual than the one identified in item 26, will not be accepted by the Agency unless a specific delegation, signed by the certifying official authorizes another individual to submit amendment requests.

It is recognized that licensees may use a consultant group, to assist in preparation of the license application, provide support to the radiation safety program, or to augment or fill the role of the RSO. If a consultant is used, specify the name of the individual or consultant group. Licenses are reminded that regardless of the role of the consultant in radiation safety program management, the licensee remains ultimately responsible for all aspects of the licensed program including the services performed by the consultant.

ITEM 3 - APPLICATION DESCRIPTION

Indicate whether the application is for a new license, and amendment or a renewal to an existing license. Provide the existing license number if appropriate.

ITEM 4 - INDIVIDUAL USER(S)

Provide the full name and title of each individual who will use or directly supervise the use of radioactive materials. Complete an NRH-5A, Supplement A and/or B for each individual listed. A copy of an Agency, Agreement State or NRC license authorizing the individual to use the materials requested may be submitted. The training and experience submitted should have been received within the past 7 years in accordance with 180 NAC 1-007.66L.

ITEM 5 - RADIATION SAFETY OFFICER (RSO)

Provide the name and title of the individual designated as Radiation Safety Officer. Submit documentation of training and experience by completing an NRH-5A, Supplement A.

ITEM 6 - RADIOACTIVE MATERIAL AND PURPOSE

180 NAC Section 007 divides radioactive material for medical use into six types of use,

180 NAC 1-007.34A, 007.36, 007. 40, 007.44, 007.46 and 007.52. Using the table format below, indicate the types of use and maximum quantify of radioactive material requested.

Table 1

Item 6b(1) Elements and mass number	Item 6b(2) Chemical and/or physical form	Item 6b(3) Maximum amount that will be possessed at any one time	Item 6b(4) Purpose for which licensed material will be used
Any radioactive material or Any radioactive material initially distributed pursuant to 003.13J or equivalent NRC or Agreement State requirements	Unsealed	_____Activity or "as needed"	Any use described in 007.34A
Any radioactive material or Any radioactive material initially distributed pursuant to 003.13J or equivalent NRC or Agreement State requirements	Unsealed	_____Activity or "as needed" Also indicate if you will be using Mo-99/Tc-99m generators	Any use described in 007.36
Any radioactive material identified in 007.40	Unsealed	_____Activity	Any use described in 007.40
Any radioactive material identified in 007.44	Any sealed source identified in 007.44	_____ Activity	Any use described in 007.44
Any radioactive material identified in 007.46	Any brachytherapy source identified in 007.46	_____ Activity	Any use described in 007.46
Cobalt - 60 or Cesium - 137	Teletherapy sealed source	Not to exceed ------ Ci per source and ------ Ci total	Any use described in 007.52

You may indicate "As needed" in the "Amount" column as shown. For 007.40 radiopharmaceuticals or 007.46 implant material, express the total amount in millicuries (mCi) or Curies (Ci) depending upon the type of procedures performed. If you intend to possess an eye applicator, list it as a separate line item on the application. Sources for a high-dose-rate remote afterloading device should be listed separately. For 007.52 teletherapy, express the total amount in Ci.

If you need other items (e.g., more radioactive material for in vitro testing than is allowed under 180 NAC 1-003.07I, depleted uranium for linear dosimetry system constancy check source, or material for in vitro, animal, or human studies), make a separate line entry for each item. (Do not list sources that are authorized by 180 NAC 1- 007.23 , "Authorization for Calibration and Reference Sources." Number each line entry consecutively following the 180 NAC 1-007 material. Each line entry must identify the radionuclide, the physical form, maximum amount on hand expressed in mCi , and the purpose for which the material will be used. If you do not want all the material listed in 180 NAC 1-007.40, 7.44, and 7.46, you must identify, line by line, the material that you do want from those sections.

When determining both individual nuclide and total quantities, all materials to be possessed at any one time under the license should be included, i.e., materials received awaiting use (new teletherapy or brachytherapy source for exchange); materials in use or possessed; and those materials classified as waste awaiting disposal or being held for decay-in-storage.

For further discussion on the purposes for which licensed material will be used for each type of medical use currently authorized, e.g., teletherapy, manual brachytherapy, refer to the appropriate licensing guidance module or appendix of this guide.

ITEM 7 - RADIATION SAFETY COMMITTEE

Responsibilities of the RSC for a limited specific license are described in 180 NAC 1-007.11, "Radiation Safety Committee." The RSC's membership is generally designated by duty title as to mandatory membership for establishment of a quorum, but some positions (typically the committee chairperson) may need specific people designated along with an alternate. The Agency considers the RSC to be a key focal point for effective management of the licensed program. The RSC acts as the administrative arm of executive management and the communication link between radiation safety staff, authorized users, supervised individuals and RSO with facility executive management. Although the RSO is typically responsible for the day-to-day operations of a radiation safety program, the RSC must maintain a constant pulse on licensed activities. The RSC is also responsible for authorizing physician users and nuclear pharmacists, and approving qualified physicists and RSOs prior to seeking an amendment to recognize this latter group of individuals.

Describe your RSC Charter and Delegation of Authority to the RSO. A RSC must be established by each medical institution as described in 180 NAC 1-007.11, unless the application is only for devices identified in 180 NAC 1-007.44. If the license application is not submitted by a medical institution (some private practices), you only need to submit the RSO delegation of authority. Appendix B1 contains a model RSC Charter and RSO Delegation of Authority.

ITEM 8 - INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAMS - THEIR TRAINING AND EXPERIENCE

Individuals responsible for the radiation safety programs include licensee senior management, the authorized users, RSO, RSC, physicists (teletherapy and brachytherapy), and nuclear pharmacists. 180 NAC 1-003.10A requires that an applicant be qualified by training and experience to use the requested licensed materials for the purposes requested in such a manner as to protect health and safety and minimize danger to life or property. 180 NAC 1-007.66 provides specific criteria for acceptable training and experience for authorized users for medical use, for the RSO, teletherapy physicist, and the nuclear pharmacist. The "Remote Afterloading Brachytherapy" module describes training and experience criteria for medical physicists responsible for remote afterloading procedures. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

8.1 - SENIOR MANAGEMENT

If the application is for medical use sited in medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply. The Agency holds the licensee responsible for the radiation safety program. Therefore, it is essential for those activities licensed within a medical institution that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability is sometimes underemphasized or not addressed in applications and often poorly understood by licensee employees and managers. Senior management should delegate to the RSO and, at a medical institution, the RSC, in writing, sufficient authority, organizational freedom, and management prerogative, to communicate and direct personnel regarding Agency regulations and/or license provisions. The licensee maintains the ultimate responsibility, nevertheless, for the conduct of licensed activities.

Licensees may contract for patient services for which they do not have in-house expertise. In those instances where the contracted service is regulated by the Agency, the licensee should be aware that the licensee remains responsible for regulatory compliance and implementation of the radiation safety program. The licensee should not assume that by hiring a contractor to perform certain tasks that it has fully satisfied all regulatory requirements or that it has somehow transferred responsibility for the licensed program to a contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the radiation safety program is effectively implemented by the appropriate individuals, to provide high confidence that radioactive material is administered as directed by the authorized user.

8.2 - AUTHORIZED USERS

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.
2. Prescription of the radiation dosage or dose and how it is to be administered or preparation of the written directive as defined in 180 NAC 1-007.02,
3. Actual use of, or direction of technologists or other paramedical personnel (e.g., physicists, dosimetrists, nurses) in the use of, radioactive material, and
4. Interpretation or results of diagnostic procedures and evaluation of results of the therapy procedures.

Numbers 1 through 4 may be delegated to a physician who is under the supervision of an authorized user. Technologists or other personnel may use radioactive material under an authorized user's supervision when permitted under applicable Federal, State or local laws. Supervision is addressed in 180 NAC 1-007.13, "Supervision."

For in vitro and animal research or other uses that do not involve the intentional exposure of humans, the list of proposed authorized users should include those individuals who will actually be responsible for the safe use of the radioactive material for the requested use. Note which user will be involved with which use by reference to Items 6 and 7 of the application. Those authorized users may direct the use of radioactive material by technologists or other individuals for the requested use.

8.2.1 - AUTHORIZED USERS FOR MEDICAL USE

1. Make a separate attachment for each authorized user. Number the attachments "ATT 8.2.1", "ATT 8.2.2., " etc. Type the full name of the individual and note, by reference to Items 6.a, 6.b, etc., which proposed uses are requested for the individual. Submit training documentation as set forth in 180 NAC 1-007.66.

2. If a physician has been previously authorized for medical use and only wants to use material permitted by the previous license, you need only to submit the previous license number or a copy of the license (if issued by an Agreement state, AEC or NRC) on which the physician was specifically named as an authorized user.

3. If a physician is certified by an organization listed in the appropriate section of 180 NAC 1-007.66, submit Supplement A (see Exhibit 2) with Items 1, 2 and 3 completed.

4. Physicians not previously authorized by the Agency, AEC, NRC or an Agreement State, and not certified by an appropriate organization must submit a complete description of their training and experience using Supplements A and B (see Exhibits 2 and 3). This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria is 180 NAC 1-007.66 is met. If the training and experience does not appear to meet the 180 NAC 1-007.66 criteria, the Agency will request further documentation.

5. Broad scope medical use applicants should submit the criteria they will use to evaluate the training and experience of authorized users. 180 NAC 1-007.66 may be used as a guide. The criteria may include a provision that allows the applicant's Radiation Safety Committee to grant case-by-case exceptions.

8.2.2 - AUTHORIZED USERS FOR NONMEDICAL USE

List the full name of each individual proposed as an authorized user for nonmedical use. Submit a complete description of the person's training and experience using Supplement A (Exhibit 2). If the individual was already identified in Item 8, no additional attachment is needed here.

For uses that do not involve the intentional exposure of humans (e.g., in vitro and animal research, calibration, dosimetry research, etc.), the list of proposed authorized users should include those individuals who will actually be responsible for the safe use of radioactive material for the requested use. This could include principal investigators, veterinarians, or physicists.

8.3 - RADIATION SAFETY OFFICER

Responsibilities of the RSO for a limited specific license are described in 180 NAC 1-007.10, "Radiation Safety Officer." The Agency considers the RSO to be the primary single individual responsible for the implementation of the radiation safety program and the day-to-day operations regardless of the number or lack of radiation safety support staff. Usually, the RSO is a full-time employee of the licensed facility; however, the Agency has authorized individuals not employed by the licensee, such as a consultant, to fill the role of the RSO or provide support to the facility RSO. Applicants and licensees must submit specific information on the reporting relationship and lines of authority between executive management, the RSC, authorized users and other facility staff, and the consultant or RSO to ensure that adequate oversight of the licensed program will be provided, and in particular, that incidents with potential safety significance are addressed in a timely and efficient manner. Appendix B1 provides a model Radiation Safety Committee charter and Radiation Safety Officer Delegation of Authority.

8.4 - PHYSICISTS

Responsibilities of physicists responsible for teletherapy and brachytherapy procedures at medical facilities are not described in 180 NAC 1 Section 007. However, training and experience criteria for teletherapy physicists are described in 180 NAC 1-007.66J. For remote after loading brachytherapy, guidance on necessary training and experience for physicists responsible for after loading patient procedures is described in the licensing module, "Remote After loading Brachytherapy," of this guide.

8.5 - AUTHORIZED NUCLEAR PHARMACISTS

Authorized nuclear pharmacist (ANP) is defined in 180 NAC 1-007.02, "Training for an authorized nuclear pharmacist", and 180 NAC 1-007.66O, "Training for an authorized nuclear pharmacist," and 180 NAC 1-007.66P, "Training for experienced nuclear pharmacists."

ITEMS 9 THROUGH 23

It is important to note that the following discussions of items 9 through 23 on training programs, facilities and equipment, and the radiation safety program including waste management provide general information applicable to all medical use programs regardless of what type of medical use is authorized (e.g., radiopharmaceutical therapy versus gamma stereotactic radiosurgery). Additional specific information unique to a particular type of use can be found in the appropriate licensing module included in this guide. You should refer to those modules to ensure that the license application addresses all requested information.

Your response to items 9 through 23 should consist of single sentences that state that you will either follow the model procedure contained in Appendix __ in Regulatory Guide 7.0, or that you have enclosed your procedure for review, or simply the notation "NA for not applicable". Before you respond to an item, read the introductory paragraphs of the referenced appendix. Short responses or "NA" responses to Items 9 through 23 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments. If you edit a model procedure solely to identify responsible individuals, equipment by name or model, room numbers, or other site-specific information, there is no need to submit that procedure for review.

ITEM 9 - INSTRUMENTATION

9.1 - SURVEY INSTRUMENTS

Submit a list of survey instruments possessed or available (if allowed by the regulations) to meet the applicable requirements described in 180 NAC 1-007.35, 180 NAC 1-007.39, 180 NAC 1-007.43, 180 NAC 1-007.51, 180 NAC 1-007.45 and 180 NAC 1-007.57. The list should include the make, model number and radiation exposure range (millirem, Rem).

9.2 - DOSE CALIBRATORS

Submit a list of dose calibrators possessed or available for use to meet the applicable requirements described in 180 NAC 1-007.19. The list should include the make, model and serial number and isotopes calibrated for.

9.3 - OTHER INSTRUMENTATION

Submit a list of other equipment similar to the items suggested in Appendix C.

ITEM 10 - CALIBRATION OF INSTRUMENTS

10a - INSTRUMENT CALIBRATION

180 NAC 1-007.20 provides the required minimum procedure for calibrating and checking survey instruments. Submit your procedures for survey instrument calibration. Provide the activity, model number, and identity for the source used for survey meter calibrations. Appendix D1 of this guide contains a model procedure for calibrating survey instruments. If calibrations are performed by a consultant, provide the license number under which calibrations are performed. Additionally, if you possess only one survey instrument to meet the criteria established in 180 NAC 1 Part 7, describe your procedure for when the survey instrument is out for calibration or repair and either routine or emergency radiation surveys need to be performed.

10b - DOSE CALIBRATOR CALIBRATION

180 NAC 1-007.19 describes requirements for the use, possession, calibration and check of dose calibrators used to measure patient dosages. Submit your procedure for calibrating the dose calibrator. Provide the manufacturer's name, model and serial number of the dose calibrator(s). Appendix D2 of this guide contains a model procedure for calibrating dose calibrators. If calibrations are performed by a consultant (e.g., geometry, linearity tests) provide the license number under which calibrations are performed. Additionally, if you possess only one dose calibrator to measure patient dosages, that are not pre-measured by a nuclear pharmacy, describe your procedure for when the dose calibrator is out for calibration or repair and measurements of patient dose are needed.

ITEM 11 - FACILITIES AND EQUIPMENT

11.1 - FACILITY DIAGRAM

Submit an annotated drawing of the room or rooms and adjacent areas where radioactive material will be stored and received. Append it as ATT 11.1. All brachytherapy source storage areas, and use areas must be in compliance with 180 NAC 1-004.15, "Compliance with Dose Limits for Individual Members of the Public". Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
2. The direction of north.
3. Room numbers and principal use of each room or area (for example, office, file, radioactive waste storage, toilet, closet, hallway).
4. Any shielding available.
5. Additional safety equipment (for example, L-blocks, fixed area monitors, or safes).
6. Occupancy of adjacent areas

Refer to the licensing modules, specific to each type of use, in this guide, for additional guidance on information required for certain facilities, particularly for teletherapy, gamma stereotactic radiosurgery, and remote after loading brachytherapy procedures.

11.2 - IMAGING EQUIPMENT

If nuclear medicine imaging equipment will be transported as part of a mobile nuclear medicine service, describe your procedure for checking the equipment to ensure it has not been damaged in transit from one location to another. See Appendix N of this guide. If you are not requesting authorization for a mobile service, indicate "NA."

11.3 - OTHER EQUIPMENT AND FACILITIES

Describe other equipment and facilities available for use and storage of material described in Item 6 if this application, other than material authorized pursuant to 180 NAC 1 Section 007. Identify as ATT.11.3.

ITEM 12 - TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

12.1 - TRAINING PROGRAM

APPLICABLE REGULATIONS: 180 NAC 1-010.03, 180 NAC 1-007.10, 180 NAC 1-007.13, 180 NAC 1-007.41, 180 NAC 1-003.16, 180 NAC 1-007.66. A model training program is provided in Appendix A; however, supplemental information specific to certain types of medical use, e.g., manual brachytherapy, is provided in the licensing modules. (Note: Item 8 above, discusses applicable training and experience criteria for authorized users, the RSO, physicists, and pharmacists.) 180 NAC 1-003.16 provides that licensees may be required , in their license, to keep records for the purpose of demonstrating compliance with the Act and the regulations.
Establish and follow written procedures for instructing individuals as required in Sections 10 and 7. Generally, these written procedures should require:

1. That individuals working in or frequenting any portion of a restricted area (physicians, technologists, physicists) be instructed in the items specified in 180 NAC 1-010.03 at the time of initial employment and at least annually thereafter.

2. That individuals be kept informed of the storage, transfer, or use of radioactive materials or of radiation, be instructed in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed.

3. That the RSO implement policies and procedures for training personnel who work in or frequent areas where radioactive materials is used or stored.

4. That a licensee, who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material.

5. That the licensee provide radiation safety instruction to all personnel caring for patients undergoing radiopharmaceutical or implant therapy.

6. That other individuals, whose duties may require them to work in the vicinity of licensed material (emergency room, custodial, security, clerical staff), be informed about radiation safety hazards and appropriate precautions at the time of their employment and at least annually thereafter.

12.2 - OTHER TRAINING PROGRAMS

Describe your training program for individuals who handle radioactive material other than the 180 NAC Section 007 material that you listed in Item 6 of this application. Identify it as ATT.12.2.

ITEM 13 - ORDERING AND RECEIVING

Submit your procedures for ordering and receiving radioactive material. Appendix E of this guide contains model procedures. You are reminded that 180 NAC 1-004.32C requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day, if it is received during non-working hours.

ITEM 14 - OPENING PACKAGES

Submit your procedures for opening packages that contain radioactive material. Appendix F of this guide contains model procedures.

ITEM 15 - GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

Submit your rules for the safe use of radiopharmaceuticals. Appendix G of this guide contains model procedures.

15.1 - ALARA PROGRAM

Submit your ALARA program. Each medical use licensee must have an ALARA program, as required in 180 NAC 1-007.09, unless the application is only for devices listed in 180 NAC 1-007.46H. If you are only applying for devices in 180 NAC 1-007.46H, indicate "NA." Appendix B3 has a model ALARA program.

15.2 - POSTING

Posting of radioactive material receipt, storage and use areas (including patient rooms used for therapy procedures) should be in compliance with 180 NAC 1-004.28, 180 NAC 1-007.42 and 180 NAC 1-007.48, except as described in 180 NAC 1-004.29.

15.3 - RECORDS

Submit your procedures for maintaining records of unit dosage use, multidose vial use, and for measuring and recording molybdenum concentration. Identify them as ATT 15.3

15.4 - OTHER SAFETY PROCEDURES

Submit safety procedures to be followed by individuals who handle radioactive material described in item 6 of this application other than material authorized pursuant to 180 NAC Section 007. Identify them as ATT.15.4.

ITEM 16 - EMERGENCY PROCEDURES

Submit your procedures in the event of a spill of radiopharmaceuticals. Appendix H of this guide contains model procedures.

ITEM 17 - AREA SURVEY PROCEDURES

Submit your procedures for conducting radiation area surveys. Appendix I of this guide contains model procedures. Supplemental information is contained in the manual brachytherapy licensing module of this guide.

ITEM 18 - RADIOACTIVE WASTE MANAGEMENT

180 NAC 1-004.33 requires that licensees dispose of licensed material by specific means. 180 NAC 1-004.38 requires that for licensed material transferred to a land disposal facility, the licensee must comply with the specific requirements in Appendix D to 180 NAC 1 004, i.e., manifest certification, and control and tracking. 180 NAC 1-007.33 specifies the requirements for handling of waste by decay-in-storage. 180 NAC 1-013.05 requires that licensees who transport licensed material or offer it for transport, comply with regulations of the U.S. Department of Transportation in 49 CFR Parts 170-178.

18.1 - WASTE DISPOSAL

Submit your procedures for radioactive waste disposal. Appendix J of this guide contains model procedures.

18.2 - DECAY-IN-STORAGE (DIS)

For isotopes of radioactive material with a half life of less than 65 days, the licensee may dispose of waste in ordinary trash as long as the following procedures are developed and adhered to:

1. Holding of radioactive material for decay a minimum of ten half lives.
2. Proper monitoring procedures.
3. Removal or obliteration of all labels.
4. Proper record keeping.

Licensees may request an exemption to authorize DIS of material with a half-life of less than 300 days to be held for no less than 10 half-lives. Storage area and survey requirements are covered in Appendix J.

18.3 - RETURNING SOURCES

The general requirements for disposal of licensed radioactive material are described in 180 NAC. 1 004.33 through 004.39. 004.38 requires that for licensed material transferred to a land disposal facility, the licensee must comply with the specific requirements in Appendix D to 180 NAC 1-004, i.e., manifest, certification , and control and tracking. Because of the nature of the material contained in brachytherapy and teletherapy sealed sources, the only option for disposal is transfer to an authorized recipient as specified in 004.38. Authorized recipients are the supplier of the sealed source, or a commercial firm licensed by the Agency to accept "radioactive waste" and another specific licensee authorized to possess the licensed material. Additionally, 180 NAC 1- 013.05 requires that licensees who transport licensed material or offer it for transport, comply with the regulations of the U.S. Department of Transportation in 49 CFR .

ITEM 19 - RADIOPHARMACEUTICAL THERAPY

Submit your procedure for radiation safety during radiopharmaceutical therapy procedures. Appendix K of this guide contains model procedures.

ITEM 20 - THERAPEUTIC USE OF SEALED SOURCES

Submit your procedures for radiation safety during brachytherapy source implant procedures. Appendix L of this guide contains model procedures. These procedures should include the availability of remote handling devices for brachytherapy

- sources contain only radioactive material with a half-life less than 30 days.
- sources contain only gas
- sources contain 100 μCi or less of beta- or gamma-emitting material or 10 μCi or less of alpha-emitting material
- sources are stored and not being used (must be leak tested before use or transfer)
- Ir-192 seeds in nylon ribbon.

The Agency requires that all sources, including those placed in storage, be leak tested every three years at a minimum. **NOTE:** Teletherapy licenses contain a leak-test condition. You should be aware that distributors of sealed sources usually supply a certificate with each source giving the results and date of the last leak test performed on the source. If you do not receive such a certificate, you may not use the source until a leak test has been performed and the results of the test have been received showing that the source is not leaking or contaminated. Thereafter, the source must be tested for leakage and contamination at intervals not to exceed 6 months.

23.1 - LICENSING CRITERIA FOR APPLICANTS THAT WILL USE A CONSULTANT TO PERFORM LEAK TESTS

State the name, address, and Agency license number of the consultant or commercial organization that will perform the entire leak-test process for you. The consultant or commercial organization should take the leak test samples (smears), evaluate the samples, and report the results to you. Specify the records of leak tests are maintained for at least 5 years after each test and describe the minimum information in these records. These records must identify the sealed source (e.g., manufacturer's name, model number, and serial number), the measured activity (in microcuries) of each test sample, the date of the test, and the name of the consultant or commercial organization that provided the service.

23.2 - LICENSING CRITERIA FOR APPLICANTS THAT WILL USE COMMERCIAL LEAK-TEST KITS

A person with adequate training and experience may use a commercial leak-test kit (in accordance with the supplier's instructions) for taking leak-test samples that are sent to the supplier for evaluation with the results reported to you, the licensee. The leak-test kit should have been approved for licensing by the Agency. Records of each leak test must be maintained for at least 5 years after each leak test, and must identify the source (i.e. manufacturer's name, model number, and serial number), the measured activity (in microcuries) of each test sample, the date of the test, the name of the person who took the samples, and the supplier's name and model number of the leak-test kit used to take the samples.

An individual identified in Item 7 who meets Agency's training and experience criteria as a user, radiation safety officer, or expert has adequate training and experience to use a commercial leak-test kit. If the individual who will use the leak-test kit is not one of those identified in Item 7, submit the person's name and a description of his or her training and experience, which the Agency staff will review on a case-by-case basis.

23.3 - LICENSING CRITERIA FOR APPLICANTS THAT WILL PERFORM THE ENTIRE LEAK-TEST PROCEDURE THEMSELVES

You should establish and agree to follow written procedures for performing the entire leak-test sequence. As a minimum, these procedures should require that:

1. Samples be taken from locations where contamination, if present, is likely to accumulate. Samples are not normally taken directly from the surface of a source, but rather from the nearest accessible surface, e.g., collimator blades.

2. Samples be taken with adequate precautions to minimize radiation exposure and spread of contamination.

3. Samples be evaluated or counted using a calibrated instrument of sufficient sensitivity and accuracy to measure 0.005 microcuries. Describe the instrument to be used to evaluate the samples and state its sensitivity and accuracy. Rather than specify the manufacturer's name and model number of the instrument, describe its characteristics (e.g., NaI(Tl) well crystal connected to a single-channel or multichannel analyzer). Survey instruments are not acceptable for evaluating leak-test samples.

4. Describe the calibration and standardization procedures and provide a sample calculation showing conversion of results to the required microcurie units.

5. Identify each individual who will take or evaluate the leak test samples and describe each person's training and experience if this information was not submitted in response to Item 7. An individual identified in Item 7 who meets Agency's training and experience criteria as a user, radiation safety officer or expert has adequate training and experience to perform the entire leak-test procedure.

6. For at least 5 years after each leak test, records of each leak test must be maintained and these records should identify the source (i.e., manufacturer's name, model number, and serial number), the measured activity (in mircrocuries) of each test sample, the date of the test, and the name of the person who performed the test.

ITEM 24 - PERSONNEL MONITORING PROGRAM

Personnel must be monitored in accordance with 180 NAC 1 Section 004. Describe your personnel occupational radiation exposure monitor program using the format given in Item 24. See Appendix P of this guide. The license application should include a statement regarding the establishment of a personnel monitoring program to ensure the exposure of all personnel is evaluated to determine whether monitoring is required to demonstrate compliance with the occupational dose limits described in the regulations. If pocket dosimeters are used to monitor personnel exposures, provide the useful range of the dosimeters; procedures and frequency for calibration and maintenance of pocket dosimeters; procedures and frequency for calibration and maintenance of pocket dosimeters as required by 180 NAC 1-004.17; and procedures for maintaining records of individuals monitored (to include frequency at which exposures on dosimeter will be recorded) in accordance with 180 NAC 1-004.46.

If nurses who handle therapy patients enter a restricted area under the circumstances described under 180 NAC 1-004.18, the licensee should indicate that these individuals will be monitored. Any monitored individual who handles radioactive sources should wear extremity monitoring in addition to a whole body badge.

ITEMS 25 + 26 - CERTIFICATION

sources and the procedures for keeping an inventory of implant sources. Additionally, describe the equipment and shielding available for the transfer and transport of brachytherapy sources from storage areas to the place of use. These procedures should address the safety instructions in 180 NAC 1-007.47.

ITEM 21 - PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

1. Submit your procedure for estimating worker dose from submersion in noble gases;
2. Submit your procedure for estimating worker dose from aerosol concentrations;
3. Submit your procedures for estimating aerosol and gas concentrations in effluents; and
4. Submit your procedures for calculating spilled gas clearance times. Appendix M of this guide contains model procedures for all these procedures.

21.1 - AIR EMISSIONS CONTROL

Licensees who possess sufficient quantities of radioactive material to exceed 180 NAC 004 air emissions limits should demonstrate a basis for compliance with the applicable requirements. Such basis could include one or more of the following:

1. Measured concentrations of radionuclides if air effluents are below Appendix B, Table 2 concentrations (and external dose < 50 mRem/yr);
2. Bounding calculations show that air effluents could not exceed Appendix B, Table 2 concentrations (and external dose < 50 mRem./yr); and
3. Dose modeling shows that dose equivalent to the individual likely to receive the highest dose does not exceed 10 mRem./yr.

Submit your basis for determining compliance with 180 NAC Part 4 air emission requirements.

ITEM 22 - PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

Submit your procedures for radioisotope use in animals including (1) a description of the animal housing facilities, (2) a copy of the instructions provided to animal caretakers for the handling of animals, animal waste, and carcasses, (3) instructions for cleaning and decontaminating animal cages, and (4) procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

ITEM 23 - PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN Item 6b

Submit your procedures for leak testing all sealed sources as required pursuant to 180 NAC 1-007.24, "Requirements for possession of sealed sources and brachytherapy sources." Since 180 NAC 1-007.46 identifies the Sr-90 eye applicator as a brachytherapy device, licensees are reminded that 180 NAC 1-007.24 also applies to Sr-90 eye applicators, to include the applicable leak tests and surveys. The leak test may be performed in house or by a contractor as long as the method is sensitive to detect 0.005 microcurie and the procedures are submitted and approved by the Agency. Appendix O of this guide contains a model procedure for leak-testing sealed sources. Further discussion on conducting leak tests by either the licensee or a contractor is provided below.

Sources do not need to be leak tested if:

If the application is for a private practice, it should be signed by a senior partner or the president. If the application is for an institution, hospital, or medical center, it must be signed by its director or chief executive officer. Identify the title of the office held by the individual who signs the application.

BEFORE SUBMITTING THE APPLICATION, REVIEW THE CONTENTS OF THE APPLICATION TO ENSURE THAT YOU HAVE RESPONDED TO EACH ITEM AND BE SURE THAT EACH PAGE THAT YOU HAVE ATTACHED TO PROVIDE SUPPLEMENTAL INFORMATION AS REQUESTED HAS AN ATTACHMENT NUMBER THAT CORRESPONDS TO THE CORRECT ITEM AND IS DATED.

4.0 LICENSE FEES

An application fee paid in full is required by subsection 180 NAC. 1-018.04 for most types of licenses. You should refer to 180 NAC. 1-018.05, "Schedule of Fees for Materials Licenses and Other Regulatory Services," to determine the amount of the fee. All application fees may be charged irrespective of the Agency's disposition of the application or your withdrawal of the application.

5. AMENDMENTS TO A LICENSE

A licensee must receive a license amendment before changing the scope of the program, and/or changing the Radiation Safety Officer or teletherapy physicist. See section 180 NAC 1-007.07 for the specific requirements. An application for an amendment must be filed as a letter and must be signed as described in Item 26. If the amendment application is the first one submitted after the effective date of the revision of 180 NAC 1 Section 7 the Agency will use this opportunity to list the Radiation Safety Officer and teletherapy physicist (if applicable) on the license. The teletherapy physicist's credentials must be submitted as part of the amendment application.

6.0 RENEWAL OF LICENSE

An application for the renewal of a license should first be filed at least 30 days before the expiration date. This will ensure that the license does not expire before final action on the application has been taken by the Agency as provided for in paragraph 180 NAC 003.19. The application for renewal may reference attachments that were previously submitted. For example, "See ATT 10.7, dated November 14, 1995."